REMARKS

Favorable reconsideration of this application is requested in view of the above amendments and following remarks.

Claim 14, which recites a non-elected group such as a pharmaceutical oral solid dosage form, has been withdrawn from consideration and further has been amended editorially.

Claim 1 has been amended editorially. Claim 6 has been amended editorially and further as supported by examples 1-4 in tables on pages 9-12 in the specification. Accordingly, withdrawn claim 10 has been amended editorially. Claim 9 has been amended editorially and further as supported by examples 1-4 in tables on pages 9-12 in the specification.

Claim 6 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claim 6 recites that the ready mix flavored composition of claim 1 further comprises a plasticizer, a colorant, and at least one of non-soluble additives other than the colorant. Thus, it is clear that the non-soluble additive is different from the colorant. Accordingly, claim 6 is clear, and this rejection should be withdrawn. Applicants do not concede the correctness of the rejection.

Claims 1-6 and 11-13 have been rejected under 35 U.S.C. 102(b) as being anticipated by Sue et al. (US Patent Application Publication No. 2002/0132006). Applicants respectfully traverse this rejection.

Applicants note that the patent application publication number of Sue et al. is 2002/0132006 instead of 2002/01320006.

Claim 1 recites a ready mix flavored composition including a polymer and a flavoring agent but no sweetening agent, and claim 1 further recites that the composition masks unpleasant taste of a solid core of the pharmaceutical oral solid dosage form. The

ready mix flavored composition is a ready-to-use composition, which includes all components for coating a solid core of a pharmaceutical oral solid dosage form, can be applied to a solid core of the dosage form when reconstituted in a solvent, and masks unpleasant taste of the solid core (see page 3, first para. under "Objective of the invention" of the specification). Because claim 1 recites that the composition masks unpleasant taste of a solid core of the pharmaceutical oral solid dosage form, the composition, which includes a polymer and flavoring agent but does not mask the unpleasant taste of the solid core, is out of the scope of claim 1.

Sue discloses coating formulations such as coatings #1-4 (see examples 2-4 on pages 7-8) and further discloses that the coatings #1-4 are applied to a core tablet in this order, i.e., the core table is coated with four different coating compositions and has the four coating layers (see paras. [0079]-[0084]). In contrast, the ready mix composition of claim 1 is a composition that is a ready-to-use composition, which indicates that include all components and can form a flavored coating by being dissolved or suspended in a solvent and applied to the solid core of the solid dosage form (see page 3, first para. under "Objective of the invention" of the specification). Thus, Sue fails to disclose the ready mix composition as claim 1 recites.

In addition, Sue discloses, in example 6, three coating layers such as a subcoat, color coat, and gloss coat, and suggests that the subcoat may improve adherence of the color coat to a naked core, and the reference merely suggests a coating composition that includes at least one layer of the three layers (see para. [0088]). As discussed above, Sue discloses the four-layer coated tablet in the examples and discloses no other examples, and thus there is no reasonable basis to assume that the color coat can be used alone as a ready mix composition as claim 1 recites.

Further, Sue suggests inclusion of peppermint oil or other flavoring agents in the color coat (see para. [0089]) and further discloses that the color coat layer may be useful for a primary odor masking coat (see *id.*). The reference, however, is silent about unpleasant taste of the solid core of the pharmaceutical oral solid dosage form and fails to disclose that the composition of example 6 can mask the unpleasant taste as a ready mix composition recited in claim 1.

Accordingly, claim 1 and claims 2-6 and 11-13, which ultimately depend from claim 1, are distinguished from Sue, and this rejection should be withdrawn.

Claims 7-9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sue et al. (US Patent Application Publication No. 2002/0132006) as applied above, in view of McCabe et al. (U.S. Patent Nol. 5,098,715). Applicants respectfully traverse this rejection.

Claims 7-9, which depend from claim 1, are distinguished from Sue for at least the same reasons as discussed for claim 1 above.

Similar to claim 1, claims 7-9 are directed to the ready mix flavored composition for film coating of a pharmaceutical oral solid dosage form. McCabe discloses a flavored thin film coating on solid oral dosage pharmaceuticals including unpleasant-tasting active ingredients that contains a sweetening agent in addition to a flavoring agent (see coln. 3, lines 51-59). McCabe further discloses that a coating dispersion formulation is prepared by suspending the components in water before coating (see example 1 at coln. 6, lines 28-40) and thus fails to disclose the ready mix flavored composition as claims 7-9 require. By having the ready mix flavored composition for film coating, all components included in the ready mix flavored composition for coating are dissolved or suspended in a solvent at one time, and this process would reduce a manufacturing time, operational errors such as weighing components incorrectly, or varieties of the contents of the components in the coating composition among batches, and the ready mix composition could provide a uniform coating composition.

In addition, McCabe discloses that the unpleasant taste of the active ingredients is masked with the flavoring agent and sweetening agent in an aqueous coating dispersion (see coln. 2, lines 53-57). McCabe is silent that the coating composition of McCabe including the flavoring agent alone can mask the unpleasant taste of the active ingredient, as claims 7-9 requires. The content of each component in the composition of McCabe is based on the composition including both flavoring agent and sweetening agent. Even if the composition of Sue were considered as the composition that can exclude the sweetening agent, which Applicants do not concede, there is no reasonable basis to combine Sue and McCabe and apply the contents of the polymer, flavoring agent, and

plasticizer of McCabe, which includes the sweetening agent, to the composition of Sue. In particular, for the content of the flavoring agent recited in claim 7, McCabe clearly discloses that the content is readily determined by balancing the goal of masking the core taste while providing a distinct characteristic of the active ingredient and the goal of providing the tablet, which is not too sweet like a candy or mint product (see coln. 5, lines 11-19). McCabe also discloses that the desired strength of the flavoring may vary depending on the type of the tablet, patient, and flavor (see *id.*). Thus, if the sweetening agent were removed from the coating of McCabe, the content of the flavoring agent in the coating would be different.

Accordingly, McCabe does not remedy the deficiencies of Sue, and this rejection should be withdrawn.

In view of the above amendments and remarks, Applicants respectfully request favorable reconsideration of this application in the form of a Notice of Allowance.

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